CORRECTION

Premarket Approval (PMA) Package for Dockets Management Branch

PMA Number P030026 Docket # 2004M-0356

Ortho-Clinical Diagnostics, Inc.

Vitros Immunodiagnostic Products Anti-HBc

IgM Reagent Pack and Vitros

Immunodiagnostic Products Anti-HBc IgM

Calibrator

Includes:

Approval Order Correction Letter Summary of Safety and Effectiveness Data (SSED) Labeling